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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/998,114	12/29/92	KEMPF	D 4681-US-F9
			EXAMINER FAN, J
EDWARD H. GORMAN, JR. ABBOTT LABORATORIES D-377/AP6D ONE ABBOTT PARK RD. ABBOTT PARK, IL 60064-3500			ART UNIT 1203
			PAPER NUMBER 6
			DATE MAILED: 07/08/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-22 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-8, 11-22 are rejected.
5. ☒ Claims 9, 10 are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-848).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Restriction under 35 USC 121 is required.

Compounds, compositions and methods of using the compounds of claims 1-22 wherein :

1. R_1 is

A. thiazolyl, oxazolyl mono-substituted by a non-heterocyclic group.

B. isoxazolyl, isothiazolyl mono-substituted by a non-heterocyclic group.

C. thiazolyl, oxazolyl mono-substituted by a heterocyclic group. Each heterocyclic represents an independent and distinct invention.

D. isoxazolyl, isothiazolyl mono-substituted by a heterocyclic group. Each heterocyclic represents an independent and distinct invention.

2. R_7 is

A. thiazolyl, oxazolyl

B. isothiazolyl, isoxazolyl

3. R_4 is

A. phenyl

B. thiazoyl, oxazolyl

The compounds of group 1A2A3A are distinct from other groups. Group 1A2A3A would not be a reference under 35 USC 103 against the compounds of additional hetero ring containing group. Further, note that the heterocyclic moieties cannot be

considered as conventional substituents, but rather form a new core of the molecule each time that they are present. Since no common core is present, the inventions are misjoined.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

During a telephone conversation with Mr. Crowley on July 1, 1993 a provisional election was made with traverse to prosecute the invention of group 1A2A3A, a single elected species of claim 9, claims 9,10,14,16,17,20,22 and the subject matter of claims 1-8, 11,12,13,15,18,19,21 readable on group 1A2A3A. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-8,11,12,13,15,18,19,21 wherein R_1, R_7, R_4 are as defined in groups other than group 1A2A3A are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Claims 1-8,11,12,13,15,18,19,21 are rejected as being drawn to improper markush groups. The deletion of the non-elected subject matter would overcome the rejection. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure how to use the invention.

The following reasons apply:

1. Applicants' disclosure constitutes an invention to experiment, that is, the disclosure "present enormous work-loads that would require undue experimentation to find proper operative chemical synthesis, reaction conditions, therapeutic mode of administration, dosage the like.

Further, with respect to the prima facie case of non-enablement, it is noted that a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical (In re Myers) or electrical elements. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more is required. In re Fisher 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Here, applicants' fail to provide those having ordinary skill in the art reasonable assurance, as by adequate representative examples, that myriad of compounds falling within the scope of the claims can be prepared and used. See In re Surrey, 370 F.2d 349, 151 USPQ 724 (CCPA 1966).

2. The data set forth in the specification relate to in vitro studies of the claimed compounds with respect to their inhibitory effect on specified enzymes. There are no in vivo studies and there is no data in the record which correlates in vitro studies with in vivo utilization and usefulness. There is nothing in the record which establishes that the claimed protease inhibitors are effective to treat AIDS in humans. Furthermore, at page 112 of the specification, the value of IC_{50} differ from 0.67 to 0.003, more than two hundred times difference. The significance of the data is not understand.

3. Enzyme inhibitory effect is very structural, steric, configurational and sequence specific. It is very much like lock and key situation. Applicants fails to provide objective evidence to substantiate the myriads of compounds are useful for the alleged utility. Note Zeffren reference.

Claims 12,13-18 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-8, 12 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The terms " cycloalkyl", "alkyl" "alkoxy" and terms which contain "alkyl", "alkoxy" are beyond the enablement since there is no carbon number limitation.

Claims 9,10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The references submitted by applicants are noted with appreciation. The examiner appreciated applicants' fax received on June 30,1993.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Fan whose telephone number is (703) 308-4705.

JTF
July 6, 1993


JANE I. FAN
PRIMARY EXAMINER
ART UNIT 12